

**REMARKS**

After entry of the amendments presented herein, claims 11, 13-20, 22, 41, and 43-48 are pending in the application. In view of the amendments are remarks set forth herein, Applicants respectfully request allowance of all pending claims.

**35 U.S.C. 102(b) Rejection**

Claims 11, 13-19, and 41 stand rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,208,031, issued to Kelly (Kelly). Applicants respectfully request reconsideration and withdrawal of this rejection.

Kelly discloses sexual lubricants that include a zinc salt, a lubricating agent such as glycerin, a thickening agent, and water. According to Kelly, an amount of zinc salt present in the composition can be determined by varying sensitivities, sexual habits, and levels of concern over sexually transmitted viruses.

Nothing in Kelly teaches or suggests any zinc concentration for the treatment of a common cold, let alone the concentration set for in the pending claims. As noted in the present application, Applicants found that the claimed concentration provides a sufficient amount of zinc at the interface between the composition and a nasal membrane. Such concentration levels are not taught or suggested by Kelly (Applicants note that the concentration that the Examiner refers to in the present Office Action is actually w/v and not w/w as set forth in the claims).

Furthermore, Kelly does not teach or suggest any motivation for including, within a composition, an agent to increase diffusion of the active substance through mucous as set forth in claim 11, from which claims 13-19 and 41 depend. Accordingly, Applicants submit that claims 11, 13-19, and 41 are patentable over the cited reference.

**35 U.S.C. 103 Rejection**

Claims 11, 13, 14, 17-20, 22, and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/05330, in the name of Koochaki et al. (Koochaki et al.), in view of

United States Patent No. Re. 33,465, issued to Eby (Eby) and Martindale, The Extra Pharmacopeia (Martindale). Applicants respectfully request reconsideration and withdrawal of this rejection.

As noted by the Examiner, Koochaki et al. generally discloses a composition containing 0.5 to about 5 wt % carboxyl-containing polymer, 0 to 1 wt% surfactant, and 0.005 to 5 wt% nasal medicament. The Examiner acknowledges, Koochaki does not disclose the use of zinc, let alone the zinc concentration set forth in all of the pending claims. Furthermore, Koochaki does not disclose a salt agent to increase diffusion of the active substance through mucous or suggest the use of such in compositions for treatment of common colds.

Eby generally discloses zinc-containing compositions for treatment of common cold symptoms. Although, Eby states that direct application of zinc compounds may be applied by nasal spray, Eby does not provide any detail, other than total weight of zinc, as to any constituents that may go into any nasal spray; indeed, the only examples provided in Eby relate to tablet or lozenge applications of zinc to an oral membrane, and not to any nasal spray. With reference to this particular case, Eby does not teach or suggest the claimed ionic zinc concentration, a salt agent to increase diffusion of the active substance through mucous, or the thickeners set forth in claim 11, from which claims 13, 14, 17-20, 22, and 41 depend.

The Examiner cites Martindale to establish that glycerin is a common pharmaceutical excipient, which is known for its lubricating and moisturizing properties. The Examiner concludes that the addition of glycerin in the nasal pharmaceutical product and system would have been expected to provide additional moisturizing and/or lubricating properties, which would have been advantageous for a product intended for intranasal use. Applicants disagree with this analysis.

As a preliminary matter, Applicants note that none of the cited references teaches or suggests that moisturizing a nasal membrane of a subject suffering from symptoms of a common cold (e.g., a stuffed nose) is desirable. Applicants thus submit that the Examiner's addition of glycerin as a moisturizing agent to the teachings of Koochaki et al. and/or Eby results from improper hindsight, and Applicants therefore request reconsideration and withdrawal of this rejection.

As noted in the present application, the addition of glycerin to compositions of the present invention facilitates maintaining an active ingredient in an ionic state and allows ions to diffuse through the composition. The glycerin also has the ability to dissolve into and permeate mucous and the nasal epithelial membrane, carrying ions with the glycerin. These advantages are nowhere taught or suggested by any of the cited references. Thus, it would not be obvious to one skilled in the art to combine Koochaki et al., Eby, and Martindale, to form the claimed invention, and, even if these references were combined, the combination does not teach or suggest each and every element. Specifically, none of the references teaches or suggests a salt agent to increase diffusion. Accordingly, Applicants submit that claims 11, 13, 14, 17-20, 22, and 41 are allowable over the cited art.

### **New Claims**

New claims 43-48 depend on allowable claim 11 and include additional elements. Applicants therefore request consideration and allowance of new claims 43-48.

**Double Patenting**

Claims 11, 13, 14, 15, 17-20, 22, and 41 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims '1-6 of U.S. Patent No. 6,673,835 in view of Martindale. In view of the amendments set forth herein, Applicants request reconsideration of this rejection.

**CONCLUSION**

In view of the foregoing remarks, Applicants believe that the pending claims are allowable over the cited art and Applicants therefore earnestly request allowance of all pending claims. The undersigned requests a telephone call at the telephone number listed below if, for any reason, the Examiner deems one or more of the pending claims unpatentable.

Applicants authorize and respectfully request that any extension of time fees due be charged to Deposit Account No. 19-2814. **This statement does NOT authorize charge of the issue fee.**

Respectfully submitted,

Date: \_\_\_\_\_

9/14/06

By: \_\_\_\_\_



Cynthia L. Pillote  
Reg. No. 42,999

CHARLES F. HAURF JR  
Reg No 33,244  
FCV

**SNELL & WILMER, L.L.P.**

One Arizona Center  
400 East Van Buren  
Phoenix, AZ 85004-2202  
Phone: (602) 382-6296  
Fax: (602) 382-6070  
cpillote@swlaw.com